



Docket No. 13282-1

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mail Stop Appeal Brief-Patents

15 Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

APPEAL BRIEF

20 (i) Real Party in Interest

The real party in interest is the assignee, Landec Corporation.

(ii) Related Appeals and Interferences

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There are no related appeals and interferences.

(iii) Status of claims

30 Claims 1-20 are pending. Claims 1-9 have been withdrawn. Claims 10 and 16-20 have been cancelled. Claims 11-15 are appealed.

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

(iv) Status of Amendments

The amendments requested in the reply to the final Office Action have been entered.

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(v) Summary of Invention

The appealed claims are directed to the requirements for successfully ripening bananas inside a sealed polymeric bag. Claim 11, which is the only independent claim, 10 claims a sealed package which contains (i) bananas which have not yet reached their climacteric (e.g. green bananas) and (ii) a packaging atmosphere around the bananas. Claim 11 has requirements for the following features.

(1) The oxygen (O_2) permeability of the container, based on weight of the bananas; thus, the O_2 permeability at 13°C per kg of bananas in the container (referred to by the abbreviation OP13/kg) must be at least 1500 15 ml/atm.24hr.(page 5, lines 1-3 and 12-19).

(2) The ratio of the carbon dioxide (CO_2) permeability of the container to the O_2 permeability of the container (referred to by the abbreviation R ratio); thus, the R ratio at 13°C must be at least 3 (page 5, lines 3-4 and 12-19).

(3) The ethylene permeability of the container, based on weight of the bananas; thus, the ethylene permeability at 13°C per kg of bananas in the container (referred to by the abbreviation EtOP13/kg) must be at least 3 times 20 the OP13/kg (page 5, lines 4-6).

(4) The packaging atmosphere around the bananas; thus the packaging 25 atmosphere must contain

(a) 14-19% O_2 ;

(b) less than 10% CO_2 ; and

(c) a total quantity of O_2 and CO_2 less than 17%

(page 15, lines 4-9).

30 The requirements for a packaging atmosphere containing 14-19% O_2 and for an OP13/kg of at least 1500 are of particular importance in this appeal.

(vi) Grounds of rejection to be reviewed on appeal

The appealed claims have been rejected under 35 U.S.C. 103 as unpatentable
5 over U.S. Patent No. 4,842,875 (hereinafter "Anderson") in view of U.S. Patent No.
5,045,331 (hereinafter "Antoon 331") and further in view of U.S. Patent No. 3,450,544
(hereinafter "Badran 544"), U.S. Patent No. 3,450,542 (hereinafter "Badran 542"), U.S.
Patent No. 6,013,293 (hereinafter "De Moor"), and EP 752378 (hereinafter "Scolaro").

10 (vii) Argument

Claims 11-15

The argument below is directed to claim 11. For the purposes of this appeal, but
15 not for the purposes of any other proceedings, Applicant will not argue for the separate
patentability of claims 12-15.

Applicant contends that the Examiner has not made a *prima facie* case for
rejecting the claims under 35 USC 103; and that if, contrary to that contention, such a
20 *prima facie* case has been made, the experimental evidence in the specification shows
that the claimed range of 14-19% O₂ achieves unexpected and valuable results relative
to the prior art, thus rebutting the *prima facie* case and establishing the patentability of
the claimed invention.

25 It is well-settled law that the burden of establishing a *prima facie* case under 35
USC 103 is on the Examiner, and that in order to establish such a case based on a
combination of references, there must be (in addition to a suggestion or motivation to
combine the references, which Applicant does not dispute for the purposes of this
appeal, but not for the purposes of any other proceedings)

30 (1) a reasonable expectation of success, and
(2) a teaching or suggestion of all the claim limitations.

In re Oertiker 24 USPQ 1443, 1444 (Fed. Cir. 1992) and in re Piasecki 223 USPQ 785, 788 (Fed. Cir. 1984).

In the present case, as will be clear from the detailed comments on the

5 references below, the references not only fail to teach all the claim limitations, but also affirmatively teach away from the requirement that the packaging atmosphere should contain 14-19% oxygen.

A. There are at least the following differences between the primary reference,
10 Anderson, and claim 11.

(1) Claim 11 requires that the packaging atmosphere contains 14 to 19% O₂. Anderson states (Table 1, column 3) that the optimum storage conditions for "banana, ripening" are an atmosphere containing 2-5 % O₂.

(2) Claim 11 requires that the sealed container has an OP13/kg of at least 1500 ml/atm.24hr. Anderson requires that his membrane should "provide a flux of O₂ approximately equal to the predicted O₂ respiration rate" (column 2, lines 45-50). The O₂ respiration rate is identified in Table 1, column 3, as 44 cc of oxygen/kg.hr at 21°C. The O₂ respiration rate per 24 hours is, therefore, 24 times as large, i.e. 1056 ml/kg.24hr at 21°C. This is far below the minimum O₂ permeability at 13°C per kg of bananas required by claim 11. The O₂ permeability of polymeric materials decreases with temperature, so that the O₂ permeability of Anderson's containers will be even less than 1056 ml/kg.24hr at 13 °C.

25 B. There are at least the following differences between Antoon 331 and claim 11.

(1) Claim 11 requires that the packaging atmosphere contains 14 to 19% O₂. Antoon 331 states (Table 1, column 3) that the optimum storage conditions for "banana, ripening" are an atmosphere containing 2-5 % O₂.

(2) Claim 11 requires that the sealed container has an OP13/kg of at least 1500 ml/atm.24hr. Antoon 331, like Anderson, requires that his panel should "provide a flux of O₂ approximately equal to the predicted O₂ respiration rate"

(column 3, lines 33-43), and the O₂ respiration rate is identified in Table 1, column 3, as 44 cc of oxygen/kg.hr at 21°C. As in Anderson, therefore, Antoon 331's containers have an O₂ permeability far below the minimum O₂ permeability required by claim 11.

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- C. There is at least the following difference between Badran 542 and claim 11.
 - (1) Claim 11 requires that the packaging atmosphere contains 14 to 19% O₂. Badran 542 states that the packaging atmosphere contains less than 7% O₂ (column 7, line 66), less than 5.5% O₂ (Claim 1), preferably 1-5.5% O₂ (claims 2 and 8, and column 3, lines 29-32), particularly 2-3% (column 7, line 70).
- D. There is at least the following difference between Badran 544 and claim 11.
 - (1) Claim 11 requires that the packaging atmosphere contains 14 to 19% O₂. The O₂ contents disclosed in Badran 544 are below the 14-19% requirement of claim 11, namely 1.4-10% for foodstuffs in general (claim 1), and 1.4-2.4%, for (ripe, not green) bananas (claim 11).
- E. There are at least the following differences between De Moor and claim 11.
 - (1) Claim 11 requires bananas which have not yet reached their climacteric. De Moor makes no reference to bananas.
 - (2) Insofar as De Moor is of any relevance to claim 11, which Applicant denies, the O₂ contents disclosed therein are below the 14-19% requirement of claim 11, namely 1-2% (column 1, line 49, for broccoli) and 5-8% (column 1, line 53, for cherries).
- F. There are at least the following differences between Scolaro and claim 11.
 - (1) Claim 11 requires that the packaging atmosphere contains 14 to 19% O₂. Scolaro states that the modified atmosphere in his containers contains 2-20%, preferably 2-6%, of oxygen (para 15, column 2, lines 46-48, and claim 1). Applicant contends, however, that insofar as Scolaro discloses or suggests the

use of an atmosphere containing 14 to 19% oxygen, Scolaro contains no enabling disclosure and should, therefore, be ignored.

It is well-settled law that a rejection cannot be based on disclosure in a reference that is not enabled (in re Hoeksma 158 USPQ 596, CCPA 1968); that a reference is not enabled if the subject matter cannot be produced without undue experimentation (Elan v. Mayo, 68 USPQ2d 1376, Fed. Cir. 2003); and that whether a prior art reference is enabled is a question of law based on underlying factual findings (Minnesota Mining v. Chemque, 303 F.3d 1294, Fed. Cir. 2002).

In the present case, the facts are clear. In Scolaro's sole specific example, one or more bananas are placed in a bag filled with a modified atmosphere which contains 2% oxygen (para 0016, column 3, line 4) and which remains substantially constant (para 0017, column 3, lines 18-20). The Anderson, Antoon 331, Badran 542, Badran 544 references summarized above, and the WO 92/02580 and Yahia references summarized below, consistently refers to the use of amounts of oxygen far below the 14-19% range required by claim 1. Since neither Scolaro itself, nor the prior art, provides any indication how one of ordinary skill in the art would put into effect Scolaro's invention when using an atmosphere containing 14-19% oxygen, it is clear that Scolaro's 2-20% range is a speculative proposal which requires undue experimentation in order to practice Scolaro's invention when using amounts of oxygen in the upper half of the 2-20% range.

(2) Claim 11 requires that the sealed container has an OP13/kg of at least 1500 ml/atm.24hr. Scolaro does not refer explicitly to the size of his containers or to the weight of the bananas therein. However, Scolaro states that the container is typically a bag made of LDPE (low density polyethylene) having a thickness of 35 micron (1.4 mil) and an oxygen permeability of 6800 cm³/m².24hr (the temperature of measurement is not given, but the conventional temperature for such measurements is about 21°C, as in the Anderson and Antoon 331 references). Taking Scolaro's Figure (which is approximately life-size) and the description of it in para 0017 as a guide, it appears that in his specific example, Scolaro used a bag about 11 by 19 cm and containing a single banana or two or

more bananas. Such a bag has a total surface area of about 0.042 m^2 (two surfaces, each about 0.11 by 0.19 m.) and a total oxygen permeability of about 285 (6800×0.042) $\text{cm}^3/24\text{hr}$. If the bag contains a single banana, which typically weighs about 0.2 kg, the oxygen permeability of the bag per kg of bananas is about $1421 \text{ cm}^3/24\text{hr}$. This figure will be lower at 13°C than that 23°C . More important is the fact that, from a practical viewpoint, it would be necessary to use a thicker film and put more than one banana in the bag. These changes would result in a package having an OP13/kg value far below the 1500 minimum required by claim 11.

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It will be clear, from the summaries above, that there is no suggestion or motivation in the references, either alone or together, to modify the primary reference, Anderson, by increasing the 2-5% oxygen level disclosed by Anderson to the 14-19% required by claim 11, or to increase the OP13/kg level disclosed by Anderson to the 1500 minimum required by claim 11. Indeed the reverse is true. For example, the secondary references, like the primary reference, Anderson, suggest an oxygen content far below the 14-19% range of claim 11 (2-5% in Antoon 331; less than 7% in Badran 542; 1.4-10% in Badran 544; and 2-6% in Scolaro, insofar as it is enabled); and/or are not concerned with bananas at all (De Moor); and/or make use of containers whose oxygen permeability is below that required by claim 11 (Anderson, Antoon 331 and Scolaro).

In connection with the failure of the references to disclose or suggest the 14-19% range of claim 11, reference may also be made to

25 (1) WO 92/02580, in which Figure 2 shows that the recommended atmosphere for bananas contains about 2-5% of oxygen; and
(2) Yahia E., 1997, Modified/controlled atmospheres for banana and plantains (*Musa spp*), pages 104-109 in A.A.Kader (Anderson) California-97 Proceedings, volume 3; Fruits other than apples and pears. Postharvest Horticultural Series 30 No. 17, University of California, Davis; in which page 104 states that bananas are very responsive to MA/CA when the fruit is at the pre-climacteric stage and that

optimum atmospheres are different for different cultivars but are about 2 to 5% oxygen; and page 107 similarly states that the optimum atmosphere composition for bananas is 2 to 5% oxygen.

Copies of the relevant pages of these references are of record.

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The Examiner's Position.

The final rejection asserts, without reference to any of the detailed disclosure of the references, that

10 *The art taken as a whole, i.e. each of the references, also teaches that respiration, and thus the effect it has on gas levels, is a function of weight, temperature, type of produce, film permeability etc. and that these variables can be manipulated to provide optimal gas atmospheres for preservation and ripening.*

15 and that

... given this background of teachings throughout the art taken as a whole, to provide the gas permeabilities and thus gas atmospheres for a particular product such as bananas is considered to have been a routine determination fairly directed by the art taken as a whole.

20 and that

... applicant is doing what the art taken as a whole fairly teaches.

and that

The specific variables, if they do vary in their specific quantities, are a function of product and conditions selected.

25

These assertions appear to be based on assumptions that

(1) "the art taken as a whole" extends beyond the disclosure of the references relied upon; and

(2) one of ordinary skill in the art would have ignored the differences identified above; would have carried out a comprehensive series of experiments, without regard to the oxygen levels recommended in the references relied upon, and in

WO02/02580 and the Yahia reference; and would thus have identified the requirements set out in claim 11.

There is no evidence in support of either of these assumptions, each of which is essential to the rejection. As the CAFC stated in *in re Zurko*, 59 USPQ 2d at 1697

5 "The Board cannot simply reach conclusions based on its own understanding or experience – or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings".

10 Rebuttal of *prima facie* Case

If, contrary to Applicant's contention, the Board finds that a *prima facie* case has been established, Applicant will rely upon the experimental evidence in the specification to show that the claimed range of 14-19 % of oxygen achieves unexpected 15 and valuable results relative to the prior art, thus rebutting the *prima facie* case and establishing the patentability of the invention. *In re Piasecki* 223 USPQ 785 (Fed. Cir. 1984).

Table 2 on page 23 of this application sets out the results of the experiments 20 described in detail on page 22. In each of these experiments, 18.1 kg of green bananas were placed in a 38 x 50 inch bags of 2.2 mils thick polyethylene. In Example C34, the bags were left open. In Examples C31-33 and 3, the bags were sealed. The sealed bags included different atmosphere control members and, therefore, differed in the extent to which oxygen could enter the bag. The bags were maintained at 13°C for 36 25 days after packing, at which time half the sealed bags in each of Examples C31-33 and 3 were opened, and all the bags were placed in a commercial ripening room for about 24 hours (i.e. in an atmosphere containing ethylene at a concentration of 500 to 1000 ppm -- see page 14, lines 16-17). The bags of bananas were then stored until 49 days after packing, at which time the bags which were still sealed were opened, and the 30 bananas inspected. As shown in Table 2, the oxygen content within the sealed bags 23 days after packing was 8.6% in Example C31, 9.8% in Example C32, 12.7% in Example

C33, and 15.5% in Example 2; although not specifically so stated in Table 2, the oxygen content in the open bags of Example C34 was of course atmospheric, i.e. about 21%. The quality of the bananas, at the end of the tests, was excellent in the example of the invention (Example 3), in which the oxygen content was within the 14-19 % range of 5 claim 11, but unsatisfactory in the comparative Examples, in which the oxygen content was lower (Examples C31-33) or higher (Example C34).

Conclusion

10 Applicant contends, in view of the facts and arguments above, that this appeal should be allowed.

15

Respectfully submitted



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(viii) CLAIMS APPENDIX to APPEAL BRIEF

15 This appendix contains a copy of the claims involved in the appeal

11. A package which comprises

- (a) a sealed container, and
- (b) within the sealed container, bananas which have not yet reached their climacteric, and a packaging atmosphere around the bananas; the sealed container having an O_2 permeability at 13 °C, per kg of bananas in the container (OP13/kg), of at least 1500 ml/atm.24 hrs, an R ratio at 13 °C of at least 3, and an ethylene permeability at 13 °C, per kg of bananas in the container (EtOP13/kg) which is at least 3 times the OP13/kg of the container; and the packaging atmosphere containing 14 to 19% of O_2 , and less than 10% of CO_2 , with the total quantity of O_2 and CO_2 being less than 17 %.

30 12. A package according to Claim 11 wherein the container includes at least one permeable control member which provides a pathway for O₂, CO₂ and ethylene to enter or leave the packaging atmosphere and which comprises a gas-permeable membrane comprising

- (a) a microporous polymeric film, and
- (b) a polymeric coating on the microporous film.

13. A package according to Claim 12 wherein the gas-permeable membrane

(i) has a P_{10} ratio, over at least one 10°C range between -5 and 25 °C of at least 1.5, and

(ii) has an oxygen permeability (OTR), at all temperatures between 13 and 25°C, of at least 2,480,000 ml/m².atm.24 hrs (160,000 cc/100 inch².atm.24 hrs).

5 14. A package according to Claim 13 wherein the microporous polymeric film comprises a network of interconnected pores having an average pore size of less than 0.24 micron, with at least 70% of the pores having a pore size of less than 0.24 micron.

10

15. A package according to Claim 14 wherein

(1) the pores in the microporous film constitute 35 to 80% by volume of the microporous film; and

(2) the microporous film comprises

15 (a) a polymeric matrix comprising (i) an essentially linear ultrahigh molecular weight polyethylene having an intrinsic viscosity of at least 18 deciliters/g, or (ii) an essentially linear ultrahigh molecular weight polypropylene having an intrinsic viscosity of at least 6 deciliters/g, or (iii) a mixture of (i) and (ii); and

20 (a) 30 to 90% by weight, based on the weight of the film, of a finely divided particulate substantially insoluble filler which is distributed throughout the film.

25 Respectfully submitted


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(ix) EVIDENCE APPENDIX to APPEAL BRIEF

15 No evidence has been submitted pursuant to 35 CFR 1.130, 1.131 or 1.132.

(x) RELATED PROCEEDINGS APPENDIX to APPEAL BRIEF

20 There are no related proceedings.

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